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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,821	09/01/1999	MICHAEL J. WARING	CV0244	5635

7590 04/04/2007

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EXAMINER	
GHALI, ISIS A D	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/341,821	WARING ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/21/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6,8-10,14,15 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 6, 8-10, 14, 15, 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 02/21/2007 after the board decision.

According to the board decision on12/21/2006 on the appeal filed 02/13/2006, the rejection of claims 1-4, 13 and 17 under 35 U.S.C. 102(b) as being anticipated by US 3,976,223 ('223) and the rejection of claims 9,19 and 20 under 35 U.S.C. 103(a) as being unpatentable over US 5,059,187 ('187) in view of US '223 have been affirmed by the board. The board set forth a new grounds of rejections for claim 8 as being anticipated by US '223. The board has reversed the rejection of claims 5, 6, 10, 14, 15 and 18 as being unpatentable under 35 U.S.C. 103(a) over US '223 in view of EP 666 081 ('081).

Accordingly, applicants canceled claims 1-4, 7, 11-13, 16, 17.

Claims 5, 6, 8-10, 14, 15, 18-20 are pending and included in the prosecution.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5, 6, 8-10, 14, 15, 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing as they recite the barrier aerosol is "self-sealing". The specification does not provide definition of what it means to be "self-sealing" or structure necessary to meet this limitation. According to the specification, page 2, lines 18-20, "because there is positive pressure in the container, the vessel can be made to be self-sealing". This aids maintenance of wound gel sterility, see page 2, lines 20-21 of the present specification. It is also stated in the present specification that when the product container is sealed with the "opening valve", number 14 of figure 1 of the present drawing, after filling and steam sterilization, "pressure medium can then be introduced into the second compartment without compromising the sterility of the product", page 4, lines 6-11; page 4, line 34-page 5, line 5. Experiments that mimicked clinical use (i.e., discharge of gel from the opening valve) were performed to show that that "micro-organisms do not proliferate in the gel contained in the barrier vessel", page 8, line 28-page 9, line 17. In view of the specification's reference to the opening valve with respect to maintaining wound gel sterility, the examiner interprets the claimed requirement that the vessel is "self-sealing" to be a property of the opening valve. Additionally, "self-sealing" is interpreted to have its "ordinary and customary meaning" (Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582, 39 USPQ2d 1573, 1576 (Fed. Cir. 1996)), i.e., to seal by itself ("self") without assistance. Making the vessel self-sealing protects the product contained in the aerosol vessel from contamination by sealing it up after the

product has been discharged. This is consistent with the vessel's purpose to package a wound gel in multi-dose packaging which minimizes contamination once opened, page 2, lines 9-11. Neither the claims nor the specification require the self-sealing opening valve to have a particular structure. In sum, the examiner construes "self-sealing barrier aerosol vessel" to be a vessel having a first compartment for containing the wound gel and second compartment, which is isolated from it, that contains pressurized gas to facilitate discharge of the wound gel from the vessel. The first compartment comprises a valve or port, through which gel can be introduced into the vessel or discharged from it, and which seals up by itself after a single dosage of gel is expelled from the vessel. However, claims must be read in view of the specification, of which they are a part. The specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term. Phillips v. AWH Corp., 415 F.3d 1303, 1315, 75 USPQ2d 1321, 1327 (Fed. Cir. 2005).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 5, 6, 8-10, 14, 15, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of EP 0 666 081 ('081), US 3,788,521 ('521) and US 3,976,223 ('223).

EP '081 teaches gel wound dressing comprising material comprising:

a) from about 0.05% to 10% by weight of natural gelling agent;

b) from about 1.0% to 10% by weight of hydrocolloid;

c) from about 5.0% to 30.0% by weight of an alkylene glycol and

d) at least 50% by weight of water.

Therefore, EP '081 teaches the gel wound dressing composition as claimed by claim 5. The gel composition of the reference can be extruded in the form of gel through a nozzle (page 2, lines 20-24; page 3, lines 14-18). The gel of the reference has viscosity of 50-800 Pas, as required by claim 18, (page 2, lines 54-55). The reference disclosed the gel conforms readily to the shape of the wound particularly when the wound includes a cavity, and that teaching suggests treating wound of sinus cavities

(page 2, lines 8-9). The wound dressing is packaged and sterilized, as required by claims 6, 10 and 15.

Although EP '081 teaches delivery of gel wound dressing from a nozzle, it does not teach delivery of the gel wound dressing from aerosol barrier.

US '521 teaches pressurized aerosol package comprises rigid container having dispensing valve, and collapsible container inside the rigid container and pressurized gas filled in between the two containers (abstract; col.3, lines 33-40, figures). The pressurized container is self-sealing according to applicants' definition to self-sealing as "because there is positive pressure in the container, the vessel can be made self sealing". The aerosol package is made large enough to provide multiplicity of one-shot applications (col.10, lines 43-44), i.e. multi-doses. Applicants disclosed at page 3, lines 34-36 that the aerosol vessel disclosed by US '521 is one of the preferred aerosol vessel used to deliver the gel of the present invention. US '521 teaches that the discharged product from the aerosol has a uniform density and maintained a predetermined physical characteristic all the life of the package (col.7, lines 47-52; col.10, lines 35-38). US '521 disclosed method for assembling the package including the steps of filling the outer container with a gas, filling the inner container with the product, followed by inserting a valve on the neck of the containers with a press fit (col.12, lines 41-53).

However, US '521 does not teach delivering gel from the disclosed aerosol package.

US '223 teaches an aerosol container containing gel comprising carboxymethyl cellulose, gelling agent and alginate. The gel comprises polyethylene glycol, which reads on gelling agent and alkylene glycols claims by claim 5 (col.6, lines 28-31, 34, 48, 63-65; col.7, lines 29-30; col.9, lines 20-23, 45-48, 51-55). The aerosol containing gel used to treat burns, which reeds on wound (col.9, lines 20-55). Therefore, the art recognized at the time of the invention that wound dressing gel can be delivered from an aerosol package. The aerosol is provided by mechanical stream break up features, i.e. self-sealing (col.2, lines 65-67). The aerosol disclosed by the reference is not a single dose container as implied by the effort made to avoid contamination of the contents during use.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing gel deliverable from a nozzle for treating cavities comprising natural gelling agent, hydrocolloid, alkylene glycol and water as disclosed by EP '081, and one having ordinary skill in the art knowing that wound dressing gels can be delivered from an aerosol package as disclosed by US '223 would have been motivated to replace the delivery means that have a nozzle with an aerosol package, and further use the aerosol package disclosed by US '521 having inner and outer container separated by pressurized gas, motivated by the teaching of US '521 that the discharged product from such as aerosol has a uniform density and maintained a predetermined physical characteristic all the life of the package, with reasonable expectation of having wound dressing gel delivered from an aerosol package having inner container and outer container separated by a pressurized gas and meanwhile the

delivered gel will have a uniform density and maintain a predetermined physical characteristic all the life of the package.

The combined teaching of the references implies method of delivery of the wound dressing gel into the wound as required by claim 15.

Regarding claims 6, 9, 10, 15, 19 and 20 that require sterilization of the gel, it is obvious to one having ordinary skill in the art at the time of the invention to sterilize any wound dressing before application to the wound to avoid contamination of the tissue already compromised by the existing disorder, with reasonable expectation to accomplish the step of sterilization of the gel composition prior or after loading into the aerosol container to obtain barrier aerosol containing sterile gel that can be applied safely to the tissue without pain with avoidance of contamination of tissue already compromised by the wound or burn.

Regarding claim 14 that teaches treating sinuses, one having ordinary skill in the art will be motivated to use the gel composition delivered by aerosol of the combined teachings of the references to treat sinuses because EP '081 suggested delivering the wound dressing gel to the body cavities, and that encompasses sinuses cavities, and one having ordinary skill in the art would have been motivated to use the aerosol because US '223 teaches aerosol gel is protected from contamination, and US '521 teaches that products delivered from pressurized aerosol will have a uniform density and maintain a predetermined physical characteristic all the life of the package.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,976,573 teaches pharmaceutical composition in the form of gel that can be sprayed into the nasal cavity including nasal sinuses, such a gel composition has relatively high viscosity between 400 to 1000 cp such that resists being cleared from the mucosal surfaces and remains on the mucosal surfaces for relatively long periods of time (abstract; col.4, lines 38-41, 60-62; col.11, lines 15-20; claim 21 and 34). The gel is sprayed using aerosol container comprises multiple doses (col.8, lines 33-38; col.9, lines 26-31). The gel composition comprises a 5-15% suspending agent including carboxymethyl cellulose that read on hydrocolloid, dispersing agent including Pluronic that reads on gelling agent and alkylene glycols, and water (col.5, lines 30-35, 67; col.6, line 1).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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IG

4/2/07

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